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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,788	11/18/2003	Alexander Andrianov	533860-99	4564

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EXAMINER

CHANDRA, GYAN

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,788	ANDRIANOV ET AL	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/19/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Addition of new claims 4 - 26 have been made of record. Claims 1-26 are pending.

Response to Arguments

Applicant's arguments filed 01/19/2005 have been fully considered but they are not persuasive. Applicants argue that glucose-substituted polyphosphazene is administered exclusively to cats and therefore has no contact with "a receptor on human cells" (page 6, last paragraph). Regnery et al teach composition of the invention comprising not only an isolated B. henselae antigen but also an adjuvant that comprises a phosphazene polymer and they define adjuvant as " any compound capable of enhancing the immune response, i.e., improving humoral, mucosal, or cellular immunity or an animal to a specific antigen (column 6, line 15-21). Since structurally the polymer of the prior art of Regnery et al and as claimed in the instant application are identical and functionally both enhance the immune response, it is reasonable to one skill of the art to inherently expect that the polymer will bind to receptor on human cells. Therefore, Regnery's teaching encompasses human as well. Further, Regnery et al teach that polyphosphazene polymers consisting of alternating phosphorous and nitrogen, separated by alternating single and double bonds. Each phosphorous atom is covalently bonded to two pendant groups ('R'), where R can be any of variety of moieties but not limited to ...carbohydrates, including glucose (column 6, line 32-67 through column 7,

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line 1-2). Pendant group 'R' can be more than one group or same kind. Carbohydrates are defined as a polyhydroxy aldehyde or ketone or derivative thereof, having the empirical formula $(CH_2O)_n$ where n is a whole number typically greater than 3 (see U S Patent No. 5,354,853 column 4, line 51-66). This includes monosaccharide, disaccharides or oligosaccharides. Monosaccharide, or simple sugars include glucose, mannose, xylose, galactose fucose, fructose, sialic acid and many more. Oligosaccharide typically contains 2-10 monosaccharide units joined together and polysaccharides contain more than 10 monosaccharide units. Thus, the teachings of Regnery encompass attaching monosaccharide or oligosaccharide as a pendent group in a polyphosphazene.

Page 8, Applicants further argue that Regnery et al do not teach that glucose-substituted polyphosphazene would work through any receptor on any human cell. Regnery et al teach preparing polyphosphazenes by attaching carbohydrates as a pendent group 'R' to induce immunity in mammals. Further, attachment of a monosaccharide or oligosaccharide, as a pendent group of a polyposphazene will raise immunity through Th1 immune response in humans.

Applicants present Exhibits A-H to present that phosphazenes ability to induce innate immunity cannot be anticipated merely because they contain a sugar moiety. It is clearly, demonstrated by Regnery that carbohydrates can be used to attach as a pendant group and a number of carbohydrates bind with mannose receptor and therefore, the polymer would inherently induce an innate immunity. Applicants do agree with the teachings of Regnery et al that carbohydrates (monosaccharide,

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oligosaccharides or polysaccharides) can be attached as a pendent group of a polyphosphazene, and when used for immunization of an animal, would work through Th1 immune response.

Claims 1-3 remain rejected as applied in the previous office action mailed on 07/12/2004, as presented below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Regnery et.al. (U.S. Patent Number 5,958,414). Regnery et. al. disclose a polymer comprising phosphazene backbone having pendant groups such as glucose, which inherently binds to a receptor on human cells that activates innate immunity including an antigen specific Th1 immune response (column 6, Lines 32-64). Regnery et. al. also, teach a composition comprising the polymer phosphazene (also referred as polyphosphazene, see column 6, lines 21-22) and an antigen for the induction of antigen specific Th1 immune response, specifically B. henselae antigen, see column 6, lines 15-31.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnery et al (U.S. Patent Number 5,958,414) in view of Staveski et al (U S Patent No. 5,354,833) or Sugimoto et al (U S Patent No. 5,759,572).

Claimed invention is drawn to a polymer comprising a polyphosphazene having a pendant group where the pendant group binds to (i) a receptor on human cell (ii) activates an antigen specific immunity, (iii) pendant group is not glucose, (iv) pendant group is selected from the group consisting of monosaccharide, oligosaccharide and polysaccharide and (v) a composition containing the polymer and (vi) a vaccine comprising the polymer.

Regnery's teachings are summarized as set forth supra. Regnery teach a polymer comprising a polyphosphazene having a pendant group as a carbohydrate and suggest that pendant group can be different (two or more) or the same. They teach a therapeutic composition comprising a polyphosphazene (column 9 –11) and use as a vaccine to raise immunity (column 11, line12-34). Regnery et al do not explicitly teach pendant group as a monosaccharide or oligosaccharide or a polysaccharide.

Staveski et al teach that a carbohydrate is a polyhydroxy aldehyde or ketone or derivative thereof, having the empirical formula $(CH_2O)_n$ where n is a whole number typically greater than 3 (column 4, line51-66). This includes monosaccharides, disaccharides or oligosaccharides. Monosaccharide or simple sugars include glucose, mannose, xylose, galactose fucose, fructose, sialic acid and many more. Oligosaccharide typically contains 2-10 monosaccharide units joined together and polysaccharides contain more than 10 monosaccharide units. They teach using saccharide conjugate for delivering to liver through sugar receptor (mannose receptor). Staveski et al do not explicitly say oligosaccharide would work by binding a mannose receptor.

Sugimoto et al teach that oligosaccharides containing 2-10 saccharide residue bind to lectin of antigen presenting cells which then induces cellular immunity for human use (column 2, line 2). They teach that oligosaccharides can be recognized by mannose receptors of macrophages.

It would have been prima facie obvious to the person of ordinary skill in the art from the teachings of Regnery et al in combination of Steveski et al to attach either

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same kind oligosaccharides as a pendant group of polyphosphazene or two different oligosaccharides as pendants to use in a composition in a vaccine to induce immunity through mannose receptor as taught by Sugimoto. The person of ordinary skill in the art would have been motivated to attach oligosaccharide as a pendant group to induce immunity with a reasonable level of success as taught by Sugimoto to the polymer polyphosphazenes of Regnery et al.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
08 April 2005


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